

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200-386 for Levamisole Hydrochloride Soluble Drench Powder used to make a drench solution for oral administration to cattle and sheep which is effective against various internal parasites. Phoenix Scientific's Levamisole Hydrochloride Soluble Drench Powder is approved as a generic copy of Schering-Plough Animal Health Corp.'s, LEVASOL (levamisole hydrochloride) Soluble Drench Powder, approved under NADA 112-051. The ANADA is approved as of December 17, 2004, and the regulations are amended in 21 CFR 520.1242a to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subject in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

**PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1242a is amended by revising paragraphs (a) and (b)(4) to read as follows:

§ 520.1242a Levamisole powder for oral solution.

(a) *Specifications.* Each package of powder contains 9.075, 11.7, 18.15, 46.8, 362.7, or 544.5 grams (g) levamisole hydrochloride.

(b) * * *

(4) No. 059130 for use of 46.8-, 362.7-, and 544.5-g packages as in paragraphs (e)(1)(i), (e)(1)(ii)(B), (e)(1)(iii), (e)(2)(i), (e)(2)(ii)(B), and (e)(2)(iii) of this section; and for use of an 18.15-g package as in paragraph (e)(3) of this section.

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Dated: January 6, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05-675 Filed 1-12-05; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HOMELAND
SECURITY****Coast Guard****33 CFR Part 110**

[CGD01-04-004]

1625-AA01

**Anchorage Grounds; Buzzards Bay,
MA**

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard hereby establishes anchorage regulations for Buzzards Bay, Nantucket Sound, and adjacent waters of Massachusetts by relocating anchorage ground "L" in Buzzards Bay to an area near Naushon Island, MA. This action is intended to increase the safety of life and property on Buzzards Bay, improve the safety of anchored vessels in anchorage "L", and provide for the overall safe and efficient flow of vessel traffic and commerce along the newly established Recommended Traffic Route for Deep Draft Vessels. This regulation will maintain the original shape and dimension of anchorage "L" but move the anchorage to a new location within Buzzards Bay.

DATES: This rule is effective February 14, 2005.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD01-02-027] and are available for inspection or copying at

First Coast Guard District, 408 Atlantic Ave., Boston, Massachusetts 02110 between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. John J. Mauro, Commander (oan), First Coast Guard District, 408 Atlantic Ave., Boston, MA 02110, Telephone (617) 223-8355, e-mail: jmauro@d1.uscg.mil.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

On April 16, 2004, we published a notice of proposed rulemaking (NPRM) entitled Anchorage Grounds; Buzzards Bay, MA in the **Federal Register** (69 FR 20568). We received one comment on the proposed rule. No public hearing was requested and none was held.

Background and Purpose

In light of significant oil spills in Rhode Island Sound in 1996 and Buzzards Bay in 2003, the Coast Guard investigated methods of improving navigational safety in Buzzards Bay. The Coast Guard conducted a Port and Waterways Safety Assessment (PAWSA) to collect input on potential navigational safety improvements in Buzzards Bay from the local maritime community. After studying the issue and collecting mariner input, the Coast Guard concluded that a Recommended Traffic Route for Deep Draft vessels in Buzzards Bay should be implemented to improve navigation safety in this area.

Presently, there are two designated anchorage grounds in Buzzards Bay; anchorage "L" and anchorage "M", whose locations are described in 33 CFR 110.140(b)(3) and 33 CFR 110.140(b)(4), respectively. The present location of anchorage "L" puts it directly in the path of the Recommended Route for Deep Draft vessels entering or leaving the Cape Cod Canal via Cleveland Ledge Channel depicted on current versions of NOAA nautical charts in the area. Thus, this rule is needed to move anchorage "L" to a new and safer location. Although the location of anchorage "L" will change, its size and shape will remain the same.

The Coast Guard has defined the anchorage areas contained herein with the advice and consent of the Army Corps of Engineers, New England District, located at 696 Virginia Rd., Concord, MA 01742.

This regulation will not exclude fishing activity or the transit of vessels in the anchorage grounds. The Coast Guard expects no increase in the amount of vessels utilizing anchorage "L" as a result of this change in its location.

Discussion of Comments and Changes

We received one letter commenting on the proposed rule. The Coalition for Buzzards Bay wrote to support the proposed new location. The language in the final rule is changed from the proposed language only to make the bounds of the anchorage more clear. The location, size, and shape of the anchorage are unaltered by the change in language.

Note: That this language varies slightly from that for anchorage "M", at 33 CFR 110.140(b)(4). We intend to issue a separate technical correction in the future to align the description of anchorage "M" with anchorage "L".

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

This conclusion is based upon the fact that there are no fees, permits, or specialized requirements for the maritime industry to utilize this anchorage area. The regulation is solely for the purpose of advancing the safety of maritime commerce.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will have minimal economic impact on vessels operated by small entities. This conclusion is based upon the fact that there are no restrictions for entry or use of the anchorage targeting small entities. This regulation only relocates one existing anchorage area.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121),

we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule will affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact John J. Mauro at the address listed in **ADDRESSES** above.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble. This rule will not impose an unfunded mandate.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

The Coast Guard has analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to

safety that might disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that Order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

The Coast Guard has considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph (34)(f) of Commandant Instruction M16475.1D, this rule is categorically excluded from further environmental documentation. A "Categorical Exclusion Determination" is available in the docket for inspection

or copying where indicated under **ADDRESSES**.

This rule relocates one existing anchorage area to the East of the Recommended Traffic Route for Deep Draft Vessels. This designated anchorage will enhance safety in the waters of Buzzards Bay, MA by relieving vessel congestion within the bay. Thus, relocating this designated anchorage would provide a safer approach to the Cape Cod Canal by deep draft vessels.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

■ For the reasons set forth in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1(g) and Department of Homeland Security Delegation No. 0170.1.

■ 2. Section 110.140(b)(3) is revised to read as follows:

§ 110.140 Buzzards Bay, Nantucket Sound, and adjacent waters, Mass.

* * * * *

(b) * * *

(3) *Anchorage L.* The area of water bounded by lines connecting the following points: 41°30'11" N, 070°48'10" W to 41°30'46" N, 070°48'45" W, to 41°32'24" N, 070°45'50" W to 41°31'48" N, 070°45'15" W and thence to start.

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Dated: December 22, 2004.

David P. Pekoske,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 05–655 Filed 1–12–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD08–05–002]

Drawbridge Operation Regulations; Vermilion River, Flanders, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a

temporary deviation from the regulation governing the operation of the SR 3073 Swing Bridge across the Vermilion River, mile 44.9, at Flanders, Lafayette Parish, Louisiana. This deviation allows the bridge to remain closed to navigation from 6 a.m. on Sunday, February 13, 2005 until 6 a.m. on Wednesday, March 16, 2005. The deviation is necessary to repair and replace the decking on the bridge.

DATES: This deviation is effective from 6 a.m. on Sunday, February 13, 2005 until 6 a.m. on Wednesday, March 16, 2005.

ADDRESSES: Materials referred to in this document are available for inspection or copying at the office of the Eighth Coast Guard District, Bridge Administration Branch, Hale Boggs Federal Building, Room 1313, 500 Poydras Street, New Orleans, Louisiana 70130–3310 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (504) 589–2965. The Bridge Administration Branch of the Eighth Coast Guard District maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: David Frank, Bridge Administration Branch, telephone (504) 589–2965.

SUPPLEMENTARY INFORMATION: The Louisiana Department of Transportation and Development (LDOTD) has requested a temporary deviation in order to remove and replace the decking on the SR 3073 Swing Bridge across the Vermilion River, mile 44.9, at Flanders, Lafayette Parish, Louisiana. The repairs are necessary to maintain the bridge in proper working condition. This temporary deviation will allow the bridge to remain in the closed-to-navigation position from 6 a.m. on Sunday, February 13, 2005 until 6 a.m. on Wednesday, March 16, 2005.

The bridge has a vertical clearance of 13.28 feet above high water, elevation 8.2 feet MSL in the closed-to-navigation position and unlimited clearance in the open-to-navigation position. The bridge has only opened 15 times in the previous five years. There were no requests to open the bridge from any vessels in 2004. During the repairs, the bridge will not be able to be opened for navigation because the swing span will be out of balance. No alternate routes are available. Based upon the information provided by the bridge owner regarding the number of bridge openings, it has been determined that this closure will not have a significant effect on vessels which use this reach of the waterway.

In accordance with 33 CFR 117.35(c), this work will be performed with all due

speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: January 6, 2005.

Marcus Redford,

Bridge Administrator.

[FR Doc. 05–735 Filed 1–12–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP Western Alaska–04–003]

RIN 1625–AA00

Safety Zone; Bering Sea, Aleutian Islands, Unalaska Island, AK

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the Bering Sea, west of and including Makushkin Bay, Unalaska Island, Alaska. The zone is needed to facilitate oil spill recovery operations related to the grounding of the merchant vessel (M/V) SELENDANG AYU, and to mitigate damage to the environment during oil spill recovery operations. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Commander, Seventeenth Coast Guard District, the Coast Guard Captain of the Port, Western Alaska, or their on-scene representative.

DATES: This rule is effective from December 11, 2004 through June 11, 2005.

ADDRESSES: Documents indicated in this preamble as being available in the docket are available for inspection and copying at Coast Guard Marine Safety Office Anchorage, 510 “L” Street, Suite 100, Anchorage, AK 99501. Normal Office hours are 7:30 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Meredith Gillman, Marine Safety Office Anchorage, at (907) 271–6700.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Any delay